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EXAMINER	
SHAW, AMANDA MARIE	
ART UNIT	PAPER NUMBER
1634	
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/765,943	NUMAJIRI, YASUYUKI	
	Examiner	Art Unit	
	Amanda Shaw	1634	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *26 October 2009*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *28,32 and 33* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *28,32 and 33* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. This action is in response to the amendment filed October 26, 2009. This action is made FINAL.

Claims 28, 32, and 33 are currently pending.

Claim 32 has been amended.

Claim Rejections - 35 USC § 103

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

3. Claims 28 and 32-33 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hogan (US 2002/0110823 Pub 8/2002 Filed 10/2001) in view of Kris (US 6238869 Issued 2001) and Beecham (US Patent 5876926 Issued 1999).

Hogan teaches a method wherein a sample from a perioperative subject is used to generate a genomic profile for that subject. Hogan teaches that in some embodiments the genomic profile includes a set of markers that provide information that can be used to determine the course of treatment (Para 0126). Hogan further teaches

that in some embodiments the genomic profile includes a set of unique genomic identifiers (e.g., a series of polymorphic non coding SNPs) used to determine the identity of the subject (Para 0134). Additionally Hogan teaches that in preferred embodiments the genomic profiles are generated by hybridizing a genomic DNA sample to a DNA microarray and detecting hybridization (Para 0167-0176 and Para 210). Genomic DNA samples are expected to include genes suitable for personal identification and disease related genes. Thus Hogan teaches a method that comprises hybridizing a solution of DNA including genes suitable for personal identification and disease related genes to a DNA microarray with probes capable of being used to identify a subject and probes capable of being used to check on the health of a subject. By reading and analyzing the hybridization pattern on the array it is possible to determine the identity of the subject and obtain health related test information for the subject. Hogan also teaches that after the sequence information has been generated the information can be stored (e.g., as digital information on a portable chip) (para 0186). Thus Hogan teaches a method further comprising recording the test information onto a medical information card (clm 29), a method further comprising writing the test information into a memory unit (clm 32), a method further comprising outputting the test information so that the test information is stored on a computer readable storage medium (clms 32 and 33). Each of these limitations are essentially saying the same thing in a different way. The teachings of Hogan (para 0186) meet each of these limitations.

Hogan does not teach a method wherein the microarray has two separated areas one of which is an area where probes of the first DNA probe group are arranged, and another of which is an area where the probes of the second group are arranged.

However Kris teaches a microarray comprising a plurality of at least two discrete regions (abstract).

Accordingly, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have modified the method of Hogan by using a microarray that has two separated arrays as suggested by Kris. One of skill in the art would have been motivated to use the array of Kris when practicing the method of Hogan because the array of Kris allows one to analyze the presence of one or more targets (i.e. genes for personal identification and disease related genes) at the same time. From the teachings of the references, it was apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing a microarray with two separate areas wherein the first area contains probes for personal identification and the second area contains probes for checking on a health condition of the subject. Therefore, modifying the method of Hogan by using a microarray that has two separated arrays was prima facie obvious to one of ordinary skill in the art at the time of the invention.

Additionally Hogan does not teach a method comprising acquiring information recorded on a medical card owned by the subject or information stored in a storage device and comparing the identification information to the identification from the microarray. Further Hogan does not teach a step of displaying a warning and inhibiting

the test information from being written into the memory unit if the comparison result of the comparison step indicates that the first identification information and the second identification information do not match (clm 32) or an inhibiting step of displaying a warning and inhibiting execution of the second reading step, the generation step, and the output step if the comparison result of the comparison step indicates that first identification information and the second identification information do not match (clm 33).

However Beecham teaches a method wherein biometric data submitted by a user is compared to stored biometric data (column 18, lines 8-20). In the instant case the biometric data submitted by the user is being interpreted as the identification information from the microarray and the stored biometric data is being interpreted as the identification information on the medical card (i.e., storage device). Beecham teaches that when the biometric data submitted by the user matches the stored biometric data then the medical data can be obtained (col 8, lines 55-65). Thus Beecham teaches a method comprising comparing the identification information on the microarray to the identification information on the medical card and releasing medical data when there is a match. Beecham further teaches that when the biometric data (identification information from the microarray) does not match stored biometric data (information on the medical ID card) a request for new or revised biometric data is sent and no test information is released until there is a match (col 18, lines 14-20). As such Beecham teaches a step of displaying a warning and inhibiting the test information from being

released if the comparison result of the comparison step indicates that the first identification information and the second identification information do not match.

Accordingly, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have modified the method of Hogan by comparing the identification information on the microarray to the identification information on the medical card before recording the patients test results on the medical card as suggested by Beecham. One of skill in the art would have been motivated to make the comparison in order to prevent someone from obtaining someone else's private medical information. Further it would have been obvious to inhibit the execution of the second reading step, the generation step, and the output step if the comparison result of the comparison step indicates that first identification information and the second identification information do not match to also prevent someone from obtaining someone else's private medical information.

4. Claims 28 and 32-33 are rejected under 35 U.S.C. 103(a) as being unpatentable over Barrett (US 2005/0064436 Filed 3/2005) in view of Kris (US 6238869 Issued 2001) and Beecham (US Patent 5876926 Issued 1999).

Barrett teaches a method wherein a SNP profile is determined for a nucleic acid sample, where the determined SNP profiled is then employed to identify the source of the sample, e.g., the subject or patient from which the sample was obtained. Barrett further teaches that the sample can also be used to screen for a condition, e.g., a

disease. In some embodiments the sample is screened for a SNP profile and a disease simultaneously using an array of probes wherein the array includes both SNP probe features and disease probe features (para 0063). Barrett teaches that the sample may be genomic DNA which is expected to include genes suitable for personal identification and disease related genes. Thus Barrett teaches a method that comprises hybridizing a DNA sample including genes suitable for personal identification and disease related genes to a DNA microarray with probes capable of being used to identify a subject and probes capable of being used to check on the health of a subject. By reading and analyzing the hybridization pattern on the array it is possible to determine the identity of the subject and obtain health related test information for the subject. Barrett further teaches that after the sequence information has been generated the information can be stored (e.g., as digital information in a database) (para 0053-0055). Thus Barrett teaches a method further comprising recording the test information onto a medical information card (clm 29), a method further comprising writing the test information into a memory unit (clm 32), a method further comprising outputting the test information so that the test information in stored on a computer readable storage medium (clms 32 and 33). Each of these limitations is essentially saying the same thing in a different way. The teachings of Barrett (paras 0053-0055) meet each of these limitations.

Barrett does not teach a method wherein the microarray has two separated areas, one of which is an area where probes of the first DNA probe group are arranged, and another of which is an area where the probes of the second group are arranged.

However Kris teaches a microarray comprising a plurality of at least two discrete regions (abstract).

Accordingly, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have modified the method of Barrett by using a microarray that has two separated arrays as suggested by Kris. One of skill in the art would have been motivated to use the array of Kris when practicing the method of Hogan because the array of Kris allows one to analyze the presence or one or more targets (i.e. genes for personal identification and disease related genes) at the same time. From the teachings of the references, it was apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing a microarray with two separate areas wherein the first area contains probes for personal identification and the second area contains probes for checking on a health condition of the subject. Therefore, modifying the method of Barrett by using a microarray that has two separated arrays was prima facie obvious to one of ordinary skill in the art at the time of the invention.

Additionally Barrett does not teach a method comprising acquiring information recorded on a medical card owned by the subject or information stored in a storage device and comparing the identification information to the identification from the microarray. Further Hogan does not teach a step of displaying a warning and inhibiting the test information from being written into the memory unit if the comparison result of the comparison step indicates that the first identification information and the second identification information do not match (clm 32) or an inhibiting step of displaying a

warning and inhibiting execution of the second reading step, the generation step, and the output step if the comparison result of the comparison step indicates that first identification information and the second identification information do not match (clm 33).

However Beecham teaches a method wherein biometric data submitted by a user is compared to stored biometric data (column 18, lines 8-20). In the instant case the biometric data submitted by the user is being interpreted as the identification information from the microarray and the stored biometric data is being interpreted as the identification information on the medical card. Beecham teaches that when the biometric data submitted by the user matches the stored biometric data then the medical data can be obtained (col 8, lines 55-65). Thus Beecham teaches a method comprising comparing the identification information on the microarray to the identification information on the medical card and releasing medical data when there is a match. Beecham further teaches that when the biometric data (identification information from the microarray) does not match stored biometric data (information on the medical ID card) a request for new or revised biometric data is sent and no test information is released until there is a match (col 18, lines 14-20). As such Beecham teaches a step of displaying a warning and inhibiting the test information from being released if the comparison result of the comparison step indicates that the first identification information and the second identification information do not match

Accordingly, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have modified the method of Barrett by comparing the

identification information on the microarray to the identification information on the medical card before recording the patients test results on the medical card as suggested by Beecham. One of skill in the art would have been motivated to make the comparison in order to prevent someone from obtaining someone else's private medical information. Further it would have been obvious to inhibit the execution of the second reading step, the generation step, and the output step if the comparison result of the comparison step indicates that first identification information and the second identification information do not match to also prevent someone from obtaining someone else's private medical information.

5. Claims 28 and 32-33 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hashmi (US 2004/0048259 Filed 9/2002) in view of Kris (US 6238869 Issued 2001) and Beecham (US Patent 5876926 Issued 1999).

Hashmi teaches a method for genetic testing of an organism and for correlating the results of the genetic testing with a unique marker (i.e. SNP profile) that unambiguously identifies the organism (Abstract). Hashmi teaches that patients sample is contacted with a first set of probes that is used in an assay designed for genetic testing and the second set of probes is used in the determination of a molecular fingerprint (para 0089). Hashmi further teaches that the patients sample may be genomic DNA which is expected to include genes suitable for personal identification and

disease related genes (para 0061). Thus Hashmi teaches a method that comprises hybridizing a DNA sample including genes suitable for personal identification and disease related genes to a DNA microarray with probes capable of being used to identify a subject and probes capable of being used to check on the health of a subject. By reading and analyzing the hybridization pattern on the array it is possible to determine the identity of the subject and obtain health related test information for the subject. Hashmi further teaches that after the sequence information has been generated the information can be stored in a database (para 0131). Thus Hashmi teaches a method further comprising recording the test information onto a medical information card (clm 29), a method further comprising writing the test information into a memory unit (clm 32), a method further comprising outputting the test information so that the test information in stored on a computer readable storage medium (clms 32 and 33). Each of these limitations is essentially saying the same thing in a different way. The teachings of Hashmi (para 0131) meet each of these limitations.

Hashmi does not teach a method wherein the microarray has two separated areas, one of which is an area where probes of the first DNA probe group are arranged, and another of which is an area where the probes of the second group are arranged.

However Kris teaches a microarray comprising a plurality of at least two discrete regions (abstract).

Accordingly, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have modified the method of Hashmi by using a microarray that has two separated arrays as suggested by Kris. One of skill in the art

would have been motivated to use the array of Kris when practicing the method of Hashmi because the array of Kris allows one to analyze the presence or one or more targets (i.e. genes for personal identification and disease related genes) at the same time. From the teachings of the references, it was apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing a microarray with two separate areas wherein the first area contains probes for personal identification and the second area contains probes for checking on a health condition of the subject. Therefore, modifying the method of Hashmi by using a microarray that has two separated arrays was prima facie obvious to one of ordinary skill in the art at the time of the invention.

Additionally Hashmi does not teach a method comprising acquiring information recorded on a medical card owned by the subject or information stored in a storage device and comparing the identification information to the identification from the microarray. Further Hogan does not teach a step of displaying a warning and inhibiting the test information from being written into the memory unit if the comparison result of the comparison step indicates that the first identification information and the second identification information do not match (clm 32) or an inhibiting step of displaying a warning and inhibiting execution of the second reading step, the generation step, and the output step if the comparison result of the comparison step indicates that first identification information and the second identification information do not match (clm 33).

However Beecham teaches a method wherein biometric data submitted by a user is compared to stored biometric data (column 18, lines 8-20). In the instant case the biometric data submitted by the user is being interpreted as the identification information from the microarray and the stored biometric data is being interpreted as the identification information on the medical card. Beecham teaches that when the biometric data submitted by the user matches the stored biometric data then the medical data can be obtained (col 8, lines 55-65). Thus Beecham teaches a method comprising comparing the identification information on the microarray to the identification information on the medical card and releasing medical data (the results of the second DNA probe group) when there is a match. Beecham further teaches that when the biometric data (identification information from the microarray) does not match stored biometric data (information on the medical ID card) a request for new or revised biometric data is sent and no test information is released until there is a match (col 18, lines 14-20). As such Beecham teaches a step of displaying a warning (i.e., the request for new or revised biometric data) and inhibiting the test information from being released if the comparison result of the comparison step indicates that the first identification information and the second identification information do not match

Accordingly, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have modified the method of Hashmi by comparing the identification information on the microarray to the identification information on the medical card before recording the patients test results on the medical card as

suggested by Beecham. One of skill in the art would have been motivated to make the comparison in order to prevent someone from obtaining someone else's private medical information. Further it would have been obvious to inhibit the execution of the second reading step, the generation step, and the output step if the comparison result of the comparison step indicates that first identification information and the second identification information do not match to also prevent someone from obtaining someone else's private medical information.

Response To Arguments

6. In the response filed October 26, 2009 the applicants traversed the rejections made over Hogan, Barrett or Hashmi in view of Kris and Beecham. The applicants state that they disagree with the Examiners interpretation of Beecham. They state that Beecham refers to the transmission of records that have been stored in a central computer facility after biometric data received from a caller is decrypted and compared with stored biometric data. Once a biometric data match has been found the associated records are transmitted by the central computer facility back to the caller. If there is no biometric data match, the call is terminated or a request for new or revised biometric data is sent. The Applicants refer to Fig 9 of Beecham. Applicants argue that it is readily apparent that if any steps comparable to the presently claimed steps of reading and generating are performed they must have taken place before the biometric data is compared. They argue that in Beecham the medical data that gets transmitted when there is a match has already been recorded in the database, i.e., the transmitted

medical data is generated and recorded before the biometric identification takes place. They state that otherwise the process would be nonsensical, especially in the context of using a single DNA microarray that contains two sets of probes.

Regarding Claim 28 this argument has been fully considered but is not persuasive. Claim 28 recites a single "reading step" which encompasses reading the hybridization pattern of the first DNA probe group and the second DNA probe. In response to applicant's argument that the references fail to show a certain feature of applicant's invention, it is noted that the feature upon which applicant relies (i.e., performing the reading step after the biometric data is compared) is not recited in the rejected claim(s). Specifically the claim recites "wherein the generation step and the recording step are performed only when the first and second identification information match in the comparing step". Further the argument that in Beechman the medical data that gets transmitted when there is a biometric data match has already been recorded in the database is not necessarily true. For instance it is possible that the database only contains the raw microarray data for the second DNA probe set and that when there is a match the raw microarray data for the second DNA probe set is analyzed to generate test information and then the test information is recorded. As discussed in the rejection it would have been obvious to one of ordinary skill in the art at the time the invention to compare the identification information on the microarray to the identification information on the medical card or other storage device before generating test information or recording the patients test results. One of skill in the art would have been motivated to make the comparison and only perform the generation step and recording step if there

was a match in order to prevent someone from accidentally obtaining someone else's private medical information.

Regarding Claim 32 this argument has been fully considered but is not persuasive. Claim 32 recites a single "reading step" which encompasses reading the hybridization pattern of the first DNA probe group and the second DNA probe. In response to applicant's argument that the references fail to show a certain feature of applicant's invention, it is noted that the feature upon which applicant relies (i.e., performing the reading step after the biometric data is compared) are not recited in the rejected claim(s). Specifically the claim requires performing the steps of analyzing the hybridization pattern of the second DNA probe group, generating test information, writing the test information into a memory unit and outputting the test information if the comparison step resulted in a match OR displaying a warning and inhibiting the test information from being written into the memory unit if there was no match. Further the argument that in Beechman the medical data that gets transmitted when there is a biometric data match has already been recorded in the database is not necessarily true. For instance it is possible that the database only contains the raw microarray data for the second DNA probe set and that when there is a match the raw microarray data for the second DNA probe set is analyzed to generate test information and then the test information is recorded. As discussed in the rejection it would have been obvious display a warning and inhibit the test information from being written if there was no match in order to prevent someone from accidentally obtaining someone else's private medical information. Further it would be obvious to analyze the second DNA probe

group, generate test information, write the test information into a memory unit, and output the test information only when there is a match because if there is a match there is a high probability that the test information belongs to the user who entered the biometric data.

Regarding Claim 33 this argument has been fully considered but is not persuasive. Claim 33 recites a first and second "reading step" wherein the second reading step occurs after the comparison step. The phrase "reading" is so broad that it encompasses just looking at the raw microarray data. The argument that in Beechman the medical data that gets transmitted when there is a biometric data match has already been recorded in the database is not necessarily true. For instance it is possible that the database only contains the raw microarray data for the second DNA probe set and that when there is a match the raw microarray data file is opened and read and then second DNA probe set is analyzed to generate test information and then the test information is outputted. As discussed in the rejection it would have been obvious display a warning and inhibit the reading step, the generation step and the outputting step if there was no match in order to prevent someone from accidentally obtaining someone else's private medical information. Further it would be obvious to read, analyze the second DNA probe group, generate test information, and output the test information only when there is a match because if there is a match there is a high probability that the test information belongs to the user who entered the biometric data.

Conclusion

7. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Amanda M. Shaw whose telephone number is (571) 272-8668. The examiner can normally be reached on Mon-Fri 7:30 TO 4:30. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dave Nguyen can be reached at 571-272-0731. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Amanda M. Shaw
Examiner
Art Unit 1634

/Stephen Kapushoc/
Primary Examiner, Art Unit 1634